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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Telehealth for Women

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Telehealth for Women,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

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Mail Stop 06E53A

Rockville, MD 20857

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FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Telehealth for Women*. AHRQ is conducting this technical brief pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Telehealth for Women*, including those that describe adverse events. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/products/telehealth-women/protocol

This is to notify the public that the EPC Program would find the following information on *Telehealth for Women* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
    - *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

KQ 1: For conditions related to women's reproductive health (including family planning, contraception, and sexually transmitted infection counseling):

a) What is the evidence of effectiveness of telehealth as a strategy for delivery of health care services for reproductive health?
b) What are patient preferences and patient choice in the context of telehealth utilization?
c) What is the effectiveness of patient engagement strategies for telehealth?
d) What is the impact of COVID-19 on the effectiveness of telehealth and patient engagement?
e) What are the barriers to and facilitators of telehealth for women's reproductive health in low-resources settings and populations?
f) What are the harms of telehealth for women's reproductive health?

KQ 2: For interpersonal violence (including intimate partner violence and domestic violence):

a) What is the evidence of effectiveness of telehealth as a strategy for screening and interventions for interpersonal violence?
b) What are patient preferences and patient choice in the context of telehealth utilization?
c) What is the effectiveness of patient engagement strategies for telehealth?
d) What is the impact of COVID-19 on the effectiveness of telehealth and patient engagement?
e) What are the barriers to and facilitators of telehealth for screening and interventions for interpersonal violence in low-resources settings and populations?

f) What are the harms of telehealth for screening and interventions for interpersonal violence?

Contextual Question: What guidelines, recommendations or best practices have been developed for the design and use of telehealth and virtual health technologies for women for any clinical conditions, including on patient preferences, patient choice, patient engagement, and implementation in low-resource settings?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

Tables 1 and 2 shows full eligibility criteria to identify studies that address the KQs.

Table 1. PICOTS and Corresponding Inclusion and Exclusion Criteria

	Include	Exclude
Population	Adolescent and adult women (age 13 years and older), including those who are pregnant, eligible for screening, counseling, or treatment for: KQ 1: Reproductive health services: (family planning, contraception, STI counseling) KQ 2: Interpersonal violence	• Men • Children under 13
Interventions	KQ1: Reproductive health services: • Family planning (preconception counseling and care) • Contraception (screening, counseling, provision, and follow-up care) • STI counseling KQ2: Interpersonal violence (intimate partner violence, domestic violence) KQ 1a, 1b, 1e, 1f, 2a, 2b, 2e, and 2f: Telehealth and virtual health, defined as: • Any two-way telehealth strategy intended to supplement or replace traditional in-person care (e.g. virtual visits, remote monitoring, mobile applications, at-home use of medical devices, use of a facilitator; use of patient-portal or electronic medical record) • Must include direct contact between a clinician or other provider and a patient or group of patients • Telehealth can be synchronous or asynchronous • Interventions may be comprised of a single telehealth strategy or may be delivered as telehealth packages, comprised of multiple telehealth strategies. KQ 1c, 1d, 2c, and 2d: Patient engagement strategies using telehealth and virtual health	• KQ1: Non-FDA-approved contraceptive devices, medications, and other methods that are not currently in clinical use in the U.S. as of 2021 • Telehealth clinician-to-clinician consults • Interventions without bidirectional communication between the patient and the health care team (e.g., one way email or text messages) • Peer-led interventions (no clinician involvement) • Maternity Care

	Include	Exclude
Comparators	• For effectiveness and harms (KQ 1a, 1c, 1d, 1f, 2a, 2c, 2d, 2f): Usual or in-person care or traditional care models (care provided without telehealth); telehealth + in-person care vs. in-person care alone (augmentation) • For barriers, facilitators, preferences (KQ 1b, 1e, 2b, 2e): Studies with or without comparison groups (i.e. patients' perceptions are based on comparisons of their own previous experiences) • KQ 1d and 2d: during COVID-19: Clinical services before and after COVID-19 pandemic	No comparison for effectiveness and harms
Outcomes	See Table 2.	• Outcomes not relevant to the KQs • Cost analyses • Patient knowledge/education
Clinical Setting	• Home, outpatient, primary care, or primary care-referable • Contact can be simultaneous (synchronous) or communicating across time (asynchronous) • Individuals providing care include a broad range of health care workers (physicians, nurses, pharmacists, counselors, etc.) • No geographic restriction: can be urban, suburban, or rural	Studies of health care services delivered outside of health care settings (e.g., social services, churches, schools, prisons)
Country Setting	Research conducted in the U.S. or in populations similar to U.S. populations, with services and interventions applicable to U.S. practice (i.e., countries with a United Nations HDI of "very high")	Countries with significantly different health care systems and fewer resources (e.g., low-income countries); not rated 'very high' on the 2018 HDI
Study types and designs	• RCTs • A best evidence approach will be used for considering inclusion of observational studies (non-RCT with some type of comparison): o Comparative studies including trial and observational studies, including prospective and retrospective cohort studies and before-after studies (i.e., natural experiments) o Qualitative studies that evaluate preferences, barriers/facilitators o Studies that specifically note that they were conducted during the COVID-19 pandemic (e.g. either specify they are assessing effects of COVID-19, or compare practices before and after March 2020) will be included. Studies with data that overlap this period will be considered only if results are stratified by pre-post pandemic.	Case reports, case series
Language	English language	Non-English

Abbreviations: COVID-19 = novel coronavirus; FDA = U.S. Food and Drug Administration; HDI = human development index rating; KQ = key question; RCT = randomized controlled trial; STI = sexually transmitted infection; US = United States

Table 2. Table of Outcomes

Category	Included outcomes
All conditions/services	KQ 1a and 2a: • Clinical effectiveness, patient health outcomes (see specific outcomes) • Quality of life, function KQ 1b, 1c, 1d, 2b, 2c, and 2d: Measures or descriptions of patient satisfaction, patient engagement and activation, patient choice KQ 1e and 2e: Measures or descriptions of barriers and facilitators in low-resource settings • Patient-reported outcomes: patient empowerment, engagement, and satisfaction • Measures of health care access, equity, and utilization o Rates of screening and followup; adherence; no-shows o Utilization of services • KQ 1f and 2f: Harms (e.g. missed diagnosis, incorrect diagnosis, overdiagnosis, delay in treatment, increase in redundant testing or in low-value care, mental health outcomes, stress, anxiety, loss to followup)
Family planning	• Desired pregnancy; unwanted/unintended pregnancy • Interpregnancy interval • Resource utilization
Contraception	• Reduced unintended or unwanted pregnancy and births • Increased contraceptive use/uptake • Change in contraceptive method • Reproductive health outcomes • Harms associated with contraceptive care (e.g., complications of contraceptive methods; delayed method start; unable to start method of choice; reproductive coercion)
STI counseling	• Health outcomes: o STI incidence (based on testing/biologic confirmation) o STI complications • Behavioral outcomes: o Changes in STI risk behaviors (e.g., multiple sexual partners, concurrent sexual partners, sexual partners with high STI risk, unprotected sexual intercourse or contact, sex while intoxicated with alcohol or other substances, sex in exchange for money or drugs) o Changes in protective behaviors (e.g., sexual abstinence; mutual monogamy; delayed initiation of intercourse or age of sexual debut; use of condoms, other barrier methods, or chemical barriers; or other changes in sexual behavior) • STI harms: o Health care avoidance o Psychological harms (e.g., anxiety, shame, guilt, stigma)

Category	Included outcomes

IPV	• Health outcomes
	  ○ Reduced exposure to IPV as measured by a validated instrument (e.g., Community Composite Scale), self-report frequency of abuse (e.g., number of physical/sexual assaults), or discontinuation of an unsafe relationship
	  ○ Physical morbidity caused by IPV, including acute physical trauma (e.g., fractures, dislocations)
	  ○ Mental health morbidity caused by IPV, including acute mental morbidity (e.g., stress, nightmares) and chronic mental health conditions (e.g., posttraumatic stress disorder, anxiety, depression)
	  ○ Sexual trauma, unintended pregnancy, pregnancy loss, and sexually transmitted infections
	  ○ Health care utilization attributed to physical or mental effects of IPV (e.g., rates of emergency room visits);
	  ○ Social isolation
	• Harms
	  ○ Increased abuse or other forms of retaliation; and other reported harms of screening or identification

Abbreviations: IPV = interpersonal violence; KQ = key question; STI = sexually transmitted infections

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